

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Figure 2 to include reference sign 24 as requested by the Examiner. This sheet replaces the original sheet for Figure 2.

Attachments: Replacement Sheets

Annotated Sheets Showing Changes

REMARKS/ARGUMENTS

Status of Claims

Claims 1-6, 9, 11, 12, and 20-24 are pending in the present application. Claims 2 and 24 have been amended in this response. Claims 7, 8, 10, and 13-19 were previously cancelled. No claims have been added or cancelled.

Final Office Action

In the Office Action dated 6 July 2010, the Examiner objected to the previously submitted replacement drawings because the replacement sheet had annotations and the annotated sheet was the clean copy. A corrected replacement sheet for Figure 2 is submitted to include reference numeral 24. The Applicants request that the Examiner withdraw this objection.

In the Office Action dated 6 July 2010, the Examiner objected to claim 2. The phrase “other than the comparatively radiopaque material together” was objected to grammatically. The Examiner suggested revising the phrase to read, “other than the comparatively radiopaque material, and together.” The Applicants have amended claim 2 as suggested. Withdrawal of this objection is also requested.

In the Office Action dated 6 July 2010, the Examiner rejected claim 24 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It was indicated, “the concept of having the marker element form an end portion is a separate concept from welding of the at least one marker element to at least one leg of a leg ring recited in claim 23.” Claim 24 has now been amended to depend upon claim 22 rather than claim 23. Therefore, the “separate concepts” indicated by the examiner to be present in claims 23 and 24 are now separately claimed. The Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

In the Office Action dated 6 July 2010, the Examiner again rejected claims 1-3, 6, 9, 11, 12, and 20-24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,471,721 to

Dang (hereinafter “Dang”). Under 35 U.S.C. § 103(a) the Examiner rejected claim 4 as being unpatentable over Dang as applied to claim 3, in view of Applicants' own admissions, and claim 5 as being unpatentable over Dang as applied to claim 2 in view of U.S. pat. No. 6,312,456 to Kranz et al. (hereinafter “Kranz”). The rejections relying upon Dang were the subject of a telephone interview between Mr. James Schweikert and the Examiner.

Interview Summary

A telephone interview was conducted between Mr. James Schweikert, attorney of record for the Applicants, and Examiner Gerard Higgins on 27 October 2010. The Applicants wish to thank the Examiner for the courtesies extended during the interview.

During the interview, the structural differences between a core filled wire of the present invention and a sputter coated wire of Dang were discussed. The Examiner indicated that the evidence of such differences as a result in the different methods of making the wires, as provided by a declaration by an inventor under 37 CFR 1.132 for example, would be necessary to establish the allowability of the claims. Therefore, agreement on the allowability of the claims was not reached at that time.

Arguments

Submitted herewith is a Rule 1.132 Declaration of Dr. Carsten Momma. In the Declaration, Dr. Momma indicates that the differing processes of Dang and the claimed invention will clearly provide a structural difference in the resulting product. “Filling a tube stock having cylindrically cut grooves with radiopaque material and then covering the filled grooves with a sputter coating” as called for in Dang, results in a visible seam being formed along the length of the wire where the coating has been applied. In contrast, the present application provides a stent in which at least one radiopaque marker is welded onto a radiolucent body. This process does not produce a visible seam along the length of the wire but instead forms discernable weld joints where a radiopaque marker is welded onto a radiolucent body.

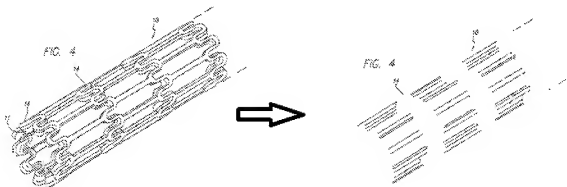
Dr. Momma further indicates that these structural differences will provide advantages in performance to the claimed invention. A stent formed according to Dang will have lesser structural integrity than the claimed stent due to the presence of the length-wise seam. Furthermore, when placed in use, the stent of Dang will be subject to a greater likelihood of defects developing. As Dr. Momma points out, stents are subjected to “extreme deformations...during expansion.” Due to these forces, proper adhesion of the coating cannot be guaranteed with Dang’s method. Additionally, defects in manufacture such as spallings and microcracks can cause corrosion, resulting in “strut breakage and separation of the radiopaque core, respectively.” In contrast, the stent of the current application is created by welding at least one radiopaque marker element onto a radiolucent stent body. The radiopaque marker is made by extruding a cover layer around a radiopaque core. This extruded cover layer makes corrosion less likely between the radiopaque marker and the body of the stent. Furthermore, the weld joints of the claimed invention will not be as susceptible to tension as the seams of Dang. Therefore, the processes of Dang and the claimed invention do not have the same or even similar resultant structures.

The Applicants also reiterate their previous arguments providing additional distinctions over the disclosure of Dang. As stated previously, the claims recite a marker element welded to at least one of the legs, and that the marker elements include a comparatively radiopaque material filling completely enclosed by a cover layer of a metal or metal compound including material other than the comparatively radiopaque material together forming a core filled wire. The legs and the marker elements are two distinctly separate claim elements. The Applicants again maintain that the struts of Dang should not be used to serve as both the legs and the marker elements of the claims.

It was stated in the previous response that claim 2 recites, in pertinent part, a stent having a carrier structure including legs defining a mesh, and having at least one marker element welded to at least one leg, and the marker element including a comparatively radiopaque material filling and completely enclosed by a cover layer of a metal or metal compound including material other than the comparatively radiopaque material together the comparatively radiopaque material and the cover layer form a core filled wire. The Examiner

indicated in the Office Action of 7 July 2010 that the claims “do not require *all* of the legs defining the mesh to be the radiolucent carrier structure...” (page 6, emphasis in original). However, the claims do require two separate structures in the “at least partially radiolucent carrier structure” and the “at least one marker element.” The claims do not allow for a single structure to act as both the carrier structure and the marker element. Marker elements that are integral to the carrier structure, as in Dang, do not read on the claims. As also stated previously, the Examiner has noted that the marker elements are integral to the carrier structure.

Furthermore, the Examiner considered the longitudinal sections of the stent 10 of Dang spanning the distance between the cylindrical marker elements read on applicants' carrier structure (Figure 4). However, without the cylindrically cut groove portions, the longitudinal sections of Dang do not form connected shape or define any apertures, as illustrated below. Removing the cylindrical portions results in longitudinal sections that merely form a series of independent unconnected parallel portions.



Applicants again point out that if the longitudinal sections of stent 10 are compared to the carrier structure a recited in claims 2 and 20 the Examiner will see that while the carrier structure, in the present applications, includes legs defining a mesh; the longitudinal sections, of Dang, (without the cylindrically cut groove portions) are merely a series of independent unconnected parallel portions which form no connected shape let alone define any apertures.

Additionally, in the Office Action, the Examiner considered the marker element (14, 13, and 11) in the form of the cylindrically shaped marker element going around the circumference of the stent to have the same resultant structure as a marker element welded to one of the legs, as claimed. Applicants again note, as stated above, this would only leave a series of parallel unconnected longitudinal members to form the carrier structure, which cannot form the carrier structure recited in the claims which includes apertures. Applicants note that the independent claims were previously amended to recite in pertinent part that the legs of the carrier structure define the apertures. It is impossible for a series of parallel unconnected longitudinal members to define apertures.

As also stated previously, a weld is defined by a localized coalescence of metal produced by heating, and as such, is a physically discernable structure. This limitation does not merely recite how two parts of the stent are joined but physically describes the resulting structure. Welding is a unique uniting process in metallurgy and leaves a discernible bond. The Examiner indicated that this statement was unsupported by the previously referenced disclosure of *Mark's Standard Handbook for Mechanical Engineers*. Particular attention is called to the statement, "A weld is defined by the AWS as a localized coalescence of metal wherein coalescence is produced by heating to suitable temperatures, with or without the application of pressure, and with or without the use of a filler metal." Clearly, one of ordinary skill in the art would recognize such "a localized coalescence of metal" as resulting in a physically discernable structure or leaving a discernable bond. Dr. Momma's Declaration also supports this contention by referring to "well defined weld joints." Although the Applicants have not provided this reference in an IDS or in an affidavit or declaration form, as noted by the Examiner in the final Office Action, the reference was not provided for the purpose of providing information material to patentability *per se*, as in an IDS, but rather to demonstrate how the term "weld" would be inherently understood by one of ordinary skill in the art to indicate the presence of a discernable feature. The Examiner has not pointed out any element of Dang that corresponds to a weld.

For the reasons provided above, Dang cannot be said to teach or suggest all the elements of the independent claims, claims 2 and 20. To anticipate a claim, a reference must

teach all elements of the claim (MPEP § 2131). Therefore, claims 1-3, 6, 9, 11, 12 and 20-24 patentably distinguish over Dang. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Dang as applied to claim 3, in view of Applicants' own admissions. For the reasons provided above, the Applicants maintain that neither Dang nor their own assertions, independently or in combination, teach or suggest all the elements of claim 4. Withdrawal of the rejection of claim 4 under 35 U.S.C. § 103(a) is respectfully requested.

Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Dang as applied to claim 2 in view of Kranz. Because Kranz was cited only for the teaching of the use of silicon carbide as an outer coating on a biocompatible stent, and because of the deficiencies of Dang in providing the remaining elements of the claims as noted above, the Applicants maintain that neither Dang nor Kranz, independently or in combination, teach or suggest all the elements of claim 5. Therefore, withdrawal of the rejection of claim 5 under 35 U.S.C. § 103(a) is also respectfully requested.

The Applicants believe that all pending claims are now in allowable form, as each is distinguishable over the cited prior art. The issuance of a Notice of Allowance is solicited.

The outstanding Office Action was electronically transmitted on 6 July 2010. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. This response is dated 6 January 2011. Therefore, the Applicants hereby request a three-month extension of time for filing this response. The Applicants additionally hereby make a conditional petition for any further necessary extensions of time for response in the event that such a petition is required. The Commissioner is authorized to charge any fee required with the filing of this paper or to credit any overpayment to Deposit Account 15-0450.

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